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| EXAMINER | |
|---|---|
| SCHWADRON, RONALD B | |

| ART UNIT | PAPER NUMBER |
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| 1644 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 08/902,692 | REA ET AL. | |
| | Examiner | Art Unit | |
| | Ron Schwadron, Ph.D. | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *49-64,67 and 70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-64,67,70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 49-64,67,70 are under consideration.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claim 49 is rejected under 35 U.S.C. 102(a) as being anticipated by Griffiths (1994). Applicants arguments have been considered and deemed not persuasive. Griffiths discloses use of the method of claim 49 to treat environmentally ill patients wherein "chemically sensitive individual" would be encompassed by the term "environmentally ill patients" (see entire reference). Lymphocytes were harvested form a blood sample of patient wherein lymphocytes would contain T and B lymphocytes (see page 7). The lymphocytes were cultured and stimulated to blast (aka propagated), lysed and the lysate was administered to the patient (see page 7). Griffiths discloses the step of claim 49(b) wherein "lymphocytes" contain T and B cells. The Griffith declaration of 4/23/08 indicates that the instant reference is a publication.

Regarding the Rea/Griffith Katz type declaration under 37 CFR 1.132, said declaration is not applicable to the instant rejection wherein the prior art has a single author and there is no indication that the other Inventor (Rea) contributed to claimed subject matter not disclosed in the instant reference. In re Katz, 687 F.2d 450, 455, 215 USPQ 14, 18 (CCPA 1982) deals with a scenario wherein additional authors of reference are "removed" in view of a declaration by Katz that he alone invented the claimed subject matter. Furthermore, the MPEP section 716.10 discloses:

*716.10 Attribution*

*Under certain circumstances an affidavit or declaration may be submitted which attempts to attribute an activity, a reference or part of a reference to the applicant. If successful, the activity or the reference is no longer applicable. When subject matter, disclosed but not claimed in a patent application filed jointly by S and another, is*

*claimed in a later application filed by S, the joint patent or joint patent application publication is a valid reference available as prior art under 35 U.S.C. 102(a), (e), or (f) unless overcome by affidavit or declaration under 37 CFR 1.131 showing prior invention (see MPEP § 715) or an unequivocal declaration by S under 37 CFR 1.132 that he or she conceived or invented the subject matter disclosed in the patent or published application.*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 49-64,67,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths in view of Youdim et al., Warren (US Patent 4,435,384), Goust et al. (US Patent 4,001,080) and Lane et al.

Griffiths discloses use of the method of claim 49 to treat environmentally ill patients wherein “chemically sensitive individual” would be encompassed by the term

"environmentally ill patients" (see entire reference). Lymphocytes were harvested from blood samples of patients wherein lymphocytes would contain T and B lymphocytes (see page 7). The lymphocytes were cultured and stimulated to blast (aka propagated), lysed and the lysate was administered to the patient (see page 7). Griffiths discloses the step of claim 49(b) wherein "lymphocytes" contain T and B cells.

Griffiths does not teach the particular steps recited in the claims 50-64. Griffiths teaches that the autologous factor can be produced by culturing/propagating PBL in vitro followed by lysis of said cells to produce a lysate containing autologous factor. The PBL are contained in a blood sample. Warren teaches the use of heparinized tubes to collect the blood sample. The use of commercially available density gradients such as HYPAQUE-FICOLL (a well known commercially available version of the agent recited in claim 51/claim 60 part(b)) using the steps recited in the claims to isolate/separate lymphocytes is well known in the art (for example see Lane et al., page 66.2). The culture of lymphocytes at 37 degrees C (aka 98.6 Fahrenheit aka body temperature) is standard operating procedure (for example Warren teaches 37 degree incubation of lymphocytes (see column 2)). Goust et al. teach use of bovine calf serum in the culture process to produce lymphocyte factors from cultured lymphocytes (see Example 3, column 5 wherein fetal calf serum is encompassed by the term bovine calf serum). Goust et al. teach that new media is added as needed (see Example 3, column 5). While Goust et al. teach that the lysate is obtained via freezing and thawing cells, Goust et al. teach that the lymphocyte factor can be produced by disrupting the cells wherein sonication is an art known procedure for disrupting cells. Warren teaches that lymphocyte factor can be produced by a variety of different methods. Centrifugation and washing of cultured cells are routine tissue culture steps for cells grown in suspension. Griffith teaches parental administration of the factor wherein subcutaneous administration is an art known form of parental administration. Youdim et al. teaches multiple administration of lymphocyte factor (see page 56, column 2). Youdim et al. teaches that skin testing (e.g. DTH) can be used to measure the response to lymphocyte factor. A routineer would have evaluated the patient pre and post treatment to determine the efficacy of treatment and to determine if further treatment was required. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Griffiths

discloses use of the method of claim 49 to treat environmentally ill patients wherein "chemically sensitive individual" would be encompassed by the term "environmentally ill patients" and the other steps recited in the claims other than 49 represent art known culture steps or modes of administration. One of ordinary skill in the art would have been motivated to do the aforementioned because Griffiths teaches the method of claim 49 and the other claims represent art known procedures that would be used to execute the method of claim 49. Griffiths discloses use of the method of claim 49 to treat environmentally ill patients wherein "chemically sensitive individual" would be encompassed by the term "environmentally ill patients" (see entire reference). Lymphocytes were harvested form a blood sample of patient wherein lymphocytes would contain T and B lymphocytes (see page 7). The lymphocytes were cultured and stimulated to blast (aka propagated), lysed and the lysate was administered to the patient (see page 7). Griffiths discloses the step of claim 49(b) wherein "lymphocytes" contain T and B cells.

Applicants arguments are as per addressed above.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron/
Ron Schwadron, Ph.D.
Primary Examiner, Art Unit 1644